

## REMARKS

Applicants have amended claim 31, and have cancelled claims 1-30, during prosecution of this patent application. Applicants are not conceding in this patent application that the subject matter encompassed by said amended and cancelled claims are not patentable over the art cited by the Examiner, since the claim amendments and cancellations are only for facilitating expeditious prosecution of this patent application. Applicants respectfully reserve the right to pursue the subject matter encompassed by said amended and cancelled claims, and to pursue other claims, in one or more continuations and/or divisional patent applications.

The Examiner rejected claims 31, 39-41 and 61 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner rejected claims 31-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by FR 7037 (ROUSSEL-UCLAF).

The Examiner rejected claims 31-34, 39-41 and 61 under 35 U.S.C. § 103(a) as allegedly being unpatentable over FR 7037 (ROUSSEL-UCLAF) in view of Grover et al. (Pediatr Res., 2002, Dec.; 52(6):907-12).

Applicant respectfully traverses the § 112, § 102 and § 103 rejections with the following arguments.

**35 U.S.C. § 112, First Paragraph: Claims 31, 39-41 and 61**

The Examiner rejected claims 31, 39-41 and 61 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner argues: "The specification discloses nicotinic acid or nicotinic acid analog where said nicotinic acid is conjugated to polyvinyl alcohol, acrylic acid ethylene co-polymer, polyethyleneglycol (PEG) or polylactic acid, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims 31, 36-41 and 61 are directed to encompass "analogs" or "a polymeric form" which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these meet the written description provision of 35 USC 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompasses a myriad of possibilities. To the extent that no structure function data is disclosed in connection with these functionally described compounds to correlate, or there is not disclosed correlation established between these functional drugs".

In response, claim 31 has been amended to delete "nicotinic acid analogs or a polymeric form thereof" and to instead recite "a nicotinic acid derivative". In addition, the substitute specification filed 12/07/2004 has been amended to state that the nicotinic acid derivatives depicted in Figures 1A-1H may be used alone in the composition of the present invention, or alternatively may be used in the composition of the present invention as conjugated with different polymers as shown in Figures 2-4. The preceding amendment to the specification is supported in, the substitute specification filed 12/07/2004, page 17, lines 17-18 which recites: "Compositions of the present invention include both nicotine, nicotinic acid analogs, and derivatives either alone or in covalent or non-covalent conjugation with polymers."

Applicants cite *In re Alonso*, USPTO 2008-1079 (Fed. Cir. October 30, 2008) as being the latest decision by the Federal Circuit how a patent application may satisfy the written description requirement with respect to a genus. This latest decision by the Federal Circuit overrides any earlier decisions by the Federal Circuit to the extent that any such earlier decisions are in conflict with this latest decision by the Federal Circuit in *In re Alonso*.

The *Alonso* court asserted that there are several alternative ways to satisfy the written description requirement in describing a genus, namely by “disclosing (1) a representative number of species in that genus; or (2) its “relevant identifying characteristics,” such as “complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Enzo Biochem, Inc. v. GenProbe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002).”

With respect to claim 31, Applicant respectfully contends that the written description requirement is satisfied, in accordance with the decision in *In re Alonso* in several different ways, via the substitute specification filed 12/07/2004, page 9, lines 24-25 in conjunction with Figures 1A-1H.

A first way in which the written description requirement is satisfied for claim 31 in accordance with the decision in *In re Alonso* is the identification of “a representative number of species” of the genus of “a nicotinic acid derivative” in Figures 1A-1H, namely the species of metals, esters, amides, anhydrides, thioester, and ring derivatives.

A second way in which the written description requirement is satisfied for claim 31 in accordance with the decision in *In re Alonso* is a depiction of “complete or partial structure” for various classes of nicotinic acid derivatives in Figures 1A-1H.

Based on the preceding arguments, Applicant respectfully maintains that claim 31 satisfies the written description requirement under 35 USC 112, first paragraph, as does claims 39-41 and 61 via the dependence of 39-41 and 61 on claim 31.

Accordingly, Applicant respectfully requests that the rejection of claims 31, 39-41 and 61 under 35 U.S.C. § 112, first paragraph be withdrawn.

**35 U.S.C. § 102(b): Claims 31-34**

The Examiner rejected claims 31-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by FR 7037 (ROUSSEL-UCLAF).

Applicant respectfully contends that FR 7037 does not anticipate claim 31, because FR 7037 does not teach each and every feature of claim 31. For example, FR 7037 does not teach a composition comprising both *nicotine* (or a polymeric form thereof) and a nicotinic acid derivative as required by claim 31. Applicant asserts that FR 7037 does not mention nicotine.

Based on the preceding arguments, Applicant respectfully maintains that FR 7037 does not anticipate claim 31, and that claim 31 is in condition for allowance. Since claims 32-34 depend from claim 31, Applicant contends that claims 32-34 are likewise in condition for allowance.

**35 U.S.C. § 103(a): Claims 31-34, 39-41 and 61**

The Examiner rejected claims 31-34, 39-41 and 61 under 35 U.S.C. § 103(a) as allegedly being unpatentable over FR 7037 (ROUSSEL-UCLAF) in view of Grover et al. (Pediatr Res., 2002, Dec.; 52(6):907-12).

Applicant respectfully contends that claim 31 is not unpatentable over FR 7037 in view of Grover, because FR 7037 in view of Grover does not teach or suggest each and every feature of claim 31. For example, FR 7037 in view of Grover does not teach or suggest a composition comprising both *nicotine* (or a polymeric form thereof) and a nicotinic acid derivative as required by claim 31. Applicant asserts that FR 7037 does not mention nicotine. Applicant further asserts that Grover does not mention nicotine.

Based on the preceding arguments, Applicant respectfully maintains that claim 31 is not unpatentable over FR 7037 in view of Grover, and that claim 31 is in condition for allowance. Since claims 32-34, 39-41 and 61 depend from claim 31, Applicant contends that claims 32-34, 39-41 and 61 are likewise in condition for allowance.

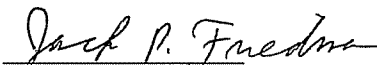
## CONCLUSION

Based on the preceding arguments, Applicant respectfully believes that all pending claims and the entire application meet the acceptance criteria for allowance and therefore request favorable action. If the Examiner believes that anything further would be helpful to place the application in better condition for allowance, Applicant invites the Examiner to contact Applicant's representative at the telephone number listed below. The Director is hereby authorized to charge and/or credit Deposit Account 19-0513.

Respectfully submitted,  
FOR: MOUSA-6043

BY:

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